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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/029,543 12/08/98 RACHAMAN E 3103/44139

HM12/0524
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WASHINGTON DC 20005

EXAMINER

OWENS JR, H

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

05/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/029,543

Applicant(s)

Rachaman et al

Examiner

Howard Owens

Group Art Unit

1623

☒ Responsive to communication(s) filed on Feb 28, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 15-40 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 15-40 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Response to Arguments

The following is in response to the amendment filed 2-28-00:

An action on the merits of claims 15-40 is contained herein

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-14 have been canceled by applicant, hence any rejections pertaining to these claims have been overcome.

Claim Objections

The objection to the specification has been overcome through applicant's amendment.

35 U.S.C. 101

Claims 35, 37 and 40 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).
below.

35 U.S.C. 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 15, 17, 31-40 are rejected under 35 U.S.C. 112,
second paragraph, as being indefinite for failing to particularly
point out and distinctly claim the subject matter which applicant
regards as the invention.

In claim 15, it is unclear what the terms "phosphoryl-sugar
group transporter recognition moiety" represents in the instant
claim. Applicant should clearly set forth (as in the case of
claim 16, what compounds are represented by this terminology).
Moreover, the Markush terminology for variables A and Q is
unclear in that the language is not selective for one member from
the group. For instance, the variable A as instantly drafted is
simultaneously alkylene, alkenylene and alkynylene as opposed to
one of these member selected from the instant Markush group.
Accordingly, claims 17 and 31-40 are rejected as well as they
fail to obviate the rejections set forth in the parent claim.

Claim 30 recites the limitation "the PYR-hydrocarbyl moiety"
in claim 16. There is insufficient antecedent basis for this
limitation in the claim. Moreover, for clarity, use of the
abbreviation "PYR" in claim 30 while an accepted art abbreviation
should be set forth initially as the full written term.

Claims 35, 37 and 40 provide for the use of a pharmaceutical
composition, but, since the claim does not set forth any steps
involved in the method/process, it is unclear what method/process
applicant is intending to encompass. A claim is indefinite where
it merely recites a use without any active, positive steps
delimiting how this use is actually practiced.

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35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 15-40 are rejected under 35 U.S.C. § 103 as being unpatentable over Bodor, U.S. Patent No. 4,824,850 and Naito, JP 05339148 A2 (abstract).

Claims 15-33, 36, 38 and 39 are drawn to a 3-substituted pyridinium compound and composition thereof, wherein a sugar moiety is attached to facilitate passage of the compound through the blood brain barrier (BBB).

Claims 34 is drawn to a method of treating cholinergic disorders, glaucoma, myasthenia gravis, pretreatment of organophosphorous intoxication and treatment of urine bladder dome.

Bodor teaches the use of pyridinium derivatives and associated salts for the delivery of pharmaceuticals through the

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BBB. Bodor teaches that pyridinium derivatives and associated salts provide a generic method for specific and/or target enhanced delivery to the brain of a wide variety of centrally acting drug species (col. 5-col.7). Bodor also teaches the conjunction(indirectly or directly) of these substituted pyridinium salts with sugars or poly substituted nontoxic polyols (col. 44, lines 50-68).

Bodor however does not teach a pyridinium compound identical to that set forth by applicant in the instant claims wherein specific sugars such as fucose or mannitol are taught.

Naito teaches the use of sugars (such as galactose, lactose, glucose, arabinose, fructose, maltose, glucosamine, mannosamine and galactosamine) to allow pharmaceuticals to pass through the blood brain barrier.

It would have been *prima facie* obvious to one of ordinary skill in the art link a glycosyl moiety to the claimed pyridinium compound for the treatment of symptoms of CNS diseases.

A patentable compound or composition of matter is one that is produced by intermixture of two or more specific ingredients; and possesses properties pertaining to none of these ingredients separately, thereby accomplishing a new and useful result. Both substituted pyridinium derivatives and sugars have been shown to be agents which can successfully pass through the blood brain barrier as lone agents or in combination with other pharmaceuticals. Therefore, it would have been obvious to modify the teachings of Bodor in view of Naito to include sugars or glycosyl moieties in a pharmaceutical composition to enhance delivery of a pharmaceutical wherein the treatment of CNS, cholinergic disorders and the like is reliant upon passage of these compounds through the BBB. One of skill in the art would also expect the compounds to be beneficial in the treatment of

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the alleviation of side-effects induced by antimuscarinic tricyclic antidepressants, symptoms of peripheral cholinergic disorders, glaucoma, myasthenia gravis and the pretreatment of organophosphorous intoxication as substituted pyridinium compounds of this general formula (such as physostigmine, pyridostigmine and neostigmine) have been known in the art to display these pharmacological properties and therapeutic uses.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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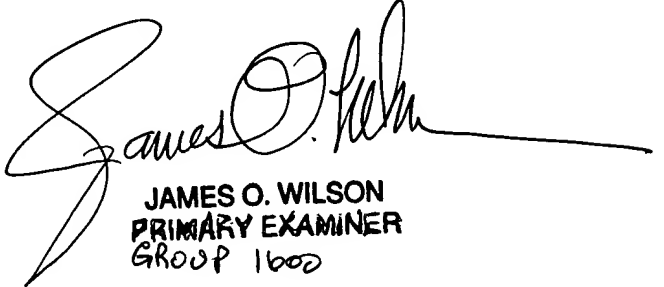
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

5 If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

10 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Howard Owens

Group 1623


JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600

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